

## **RANDOMISED CONTROLLED TRIAL OF BIOFEEDBACK FOR FAECAL INCONTINENCE**

### **Aims of Study**

Biofeedback has been extensively used in clinical practice to treat faecal incontinence and has been advocated to be "the treatment of choice" in many reviews. A systematic literature search has found 46 studies published in English using biofeedback to treat adult patients complaining of faecal incontinence (1). Overall, 49% of patients were reported as cured of their symptoms and over 70% improved. However, there has never been a high-quality randomised controlled trial (RCT) to determine the effective elements of care, nor comparing biofeedback with placebo or standard medical care (2). Our aim was to conduct a RCT to determine if exercises or biofeedback were the operant for change.

### **Methods**

171 consecutive patients with faecal incontinence to solid or liquid stool were assessed by anal ultrasound and then stratified to structurally intact or disrupted anal sphincter muscles. Within each of these two groups they were then randomised to one of four groups: (a) standard medical/nursing care (advice) (b) advice plus verbal instruction on sphincter exercises (c) hospital based computer-assisted sphincter pressure biofeedback (d) hospital biofeedback plus use of a home EMG biofeedback device. Outcome measures immediately and at one year included a bowel diary, symptom questionnaire, continence score, patient's rating of change, quality of life (SF36 and disease specific), psychological status (HAD), and anal manometry. Randomisation was successful in achieving broadly similar groups on important criteria. Recruits had a median age of 56 years (range 26-85) and had been incontinent of faeces for a median of 4 years (range 2 months to 59 years).

### **Results**

Patients had a median of 5 sessions. 82% completed the protocol. Improvement or cure occurred in groups a to d respectively: 80%, 83%, 81%, and 76% ( $p=NS$ ). Overall, 75% of patients reported symptomatic improvement and 5% were "cured" by their own assessment. Median rating of change in symptoms was +3 on a scale of -5 to +5 and median satisfaction with outcome was 8 on a 0-10 scale (10 = best outcome). Benefit was maintained for all groups at one year, with only a minimal reduction in ratings. For all groups combined, episodes of incontinence decreased from a median 2 to 0 per week ( $p<0.001$ ). Urgency and the frequency of urge and passive faecal incontinence decreased ( $p = <0.001$ ). Before treatment 47% of patients rated the impact of symptoms on their life as "quite a lot" or "a great deal"; after treatment this was 19% of the cohort ( $p = < 0.001$ ). Continence score (worst = 20) decreased from median 11 to 8 ( $p = <0.001$ ). Disease specific quality of life, SF36 (vitality, social functioning and mental health), and HAD (anxiety and depression) all significantly improved. Patients demonstrated improved resting, squeeze and sustained squeeze pressures (all  $p = <0.002$ ). None of these improvements differed between groups. The hypothesis had been that exercises would enhance outcome and biofeedback would improve outcomes yet further. There was no indication of a trend in this direction, with group 1 improving as much as all other groups. Outcome was not correlated with any of the factors examined (including prior structure or function of the anal sphincter), except age (older patients fared better) and weight (heavier patients did less well). Patients commented in detail on what they felt to be the effective elements of this "package" of care. Comments were in four broad categories: understanding of the condition; practical advice leading to improved coping strategies (e.g. diet and skin care); the experimental intervention (patients ascribed change to whatever they had been asked to do); and the nurse-patient interaction (feeling able to discuss this taboo problem and receiving support).

### **Conclusions**

Conservative therapy for faecal incontinence improves continence, quality of life, psychological well being, and anal sphincter function. Benefit is maintained in the medium term. The patient-therapist interaction and improved coping strategies appear to be most important, rather than performing exercises or receiving physiological feedback of sphincter function (biofeedback).

### **References**

1. (2001) Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults - a

systematic review. *Alimentary Pharmacology & Therapeutics* **15**, 1147-1154.

2. (2000) Effectiveness of biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane electronic library of systematic reviews*.